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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/546,629

10/05/2005

Thomas Buck

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12/08/2008

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
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INDIANAPOLIS, IN 46204-5137

EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/546,629	Applicant(s) BUCK, THOMAS	
	Examiner KATHERINE L. FERNANDEZ	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 43-60 and 62-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite as they lack active, positively recited steps describing what is being practiced.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 43-60 and 62-64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In addition to inquiry of whether a claimed method falls within a judicial exception, Supreme Court precedent (*Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).) and recent Federal Court decisions, require that a claim drawn to a process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 U.S.C. 101 and is improperly directed to nonstatutory subject matter. To qualify as a 101 statutory process, the claim should (1) positively recite the

Art Unit: 3768

other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps or (2) positively recite the subject matter that is being transformed. The limitations (evaluation of the backscatter of a measurement beam, evaluation of the measurement beams for determination of at least one of the opening surface area, the volumetric flow rate, the flow volume, and any value proportional thereto) are non-statutory because they are not tied to another statutory class (such as a particular apparatus), nor do they positively recite subject matter being transformed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 61-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Nudell et al. (EP 0 421 465 A2) as cited by applicant.

With regards to claim 61, Nudell et al. disclose a device for ultrasound measurement of at least one opening surface area of a dynamic or irregular orifice through which a fluid flows, in particular blood, of the volumetric flow rate and of the flow volume through the orifice, with means for evaluation of the power spectrum of Doppler signals of a measurement beam having a spatial measurement area and of a reference beam having a spatial measurement area, wherein the spatial measurement area of the reference beam lies within the spatial measurement area of the measurement beam

Art Unit: 3768

(pg. 5, lines 1-28; pg. 3, lines 2-8; see Figure 2); wherein the device has a matrix array transducer for generating a transmit beam and for detecting the measurement beam and reference beam, and is adapted such that several measurement beams with offset spatial, partially overlapping measurement areas covering the orifice completely and at least one of one measurement beam and of several reference beams with offset spatial measurement areas can be detected and evaluated for determination at least one of the opening surface area, the volumetric flow rate, the flow volume and any value dependent thereon (pg. 6, lines 23-53, pg. 7, lines 22-32; pg.12, lines 29-41; see Figure 4A-C, 5A and 6A-C).

With regards to claim 62, Nudell et al. disclose a method for ultrasound measurement of the opening surface area of a dynamic or irregular orifice through which a fluid flows, in particular blood, and/or of the volumetric flow rate and/or flow volume through the orifice, with evaluation of the backscatter of a measurement beam having a spatial measurement area and of a reference beam having a spatial measurement area, wherein the spatial measurement area of the reference beam lies within the spatial measurement area of the measurement beam (pg. 5, lines 1-28; pg. 3, lines 2-8; see Figure 2; see abstract); wherein the measurement area of the measurement beam is moved three-dimensionally beforehand in a search mode, while Doppler signals are continuously detected and are evaluated in respect of the occurrence of a Doppler spectrum characteristic of a vena contracta, so that thereafter, for determination of at least one of the opening surface area, the volumetric flow rate, the flow volume and any value proportional thereto, the measurement area of the

Art Unit: 3768

reference beam is directed into the inside of the vena contracta of the fluid flow through the orifice and the measurement area of the measurement beam is directed into the area of the vena contracta of the fluid flow through the orifice (pg. 7, lines 11-32; see Figures 2 and 6A-C).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nudell et al. as applied to claim 62 above, and further in view of Buck (US Patent No. 6,544,181).

As discussed above, Nudell et al. meet the limitations of claim 62. However, they do not specifically disclose the limitations of instant claims 63-64. Buck et al. disclose methods and apparatus for utilizing an ultrasonic pulsed wave Doppler signal to measure the instantaneous area of a dynamic orifice through which blood is passing and/or to measure instantaneous flow rate and flow volume of blood passing through such a dynamic orifice, and identifying the region of flow which is substantially laminar. They disclose that the measurement area of the measurement beam is moved free-dimensionally beforehand in a search mode, while Doppler signals are continuously detected and evaluated in respect of the occurrence of a Doppler spectrum characteristics of a vena contracta, so that thereafter for the determination, the

Art Unit: 3768

measurement area of the reference beam is directed into the inside of the vena contracta of the fluid flow through the orifice and the measurement area of the measurement beam is directed into the area of the vena contracta of the fluid flow through the orifice (column 8, line 49 through column 9, line 21). Further, they disclose that in order to detect a vena contracta, the Doppler signal (Velocity vs. Time) is detected and the bright higher frequency bands from the Doppler signal images correspond to laminar flow (column 8, lines 59 through column 9, line 21). The vena contracta where a laminar flow predominates is located where the narrowness and cleanness of the bright narrow-band spectrum is optimized (column 9, lines 1-21). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Nudell et al. to include the step of detecting a vena contracta when the Doppler spectrum shows at least a substantially continuous or constant line of maximal speed, as taught by Buck, as the measurement beam should be focused in the area where laminar flow occurs since the Doppler power principle holds only for laminar flow, and the flow is substantially laminar (i.e high velocity) at the vena contracta (column 2, lines 22-43; column 3, lines 5-12).

Response to Arguments

9. Applicant's arguments with respect to claims 43-64 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Art Unit: 3768

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768